EXHIBIT "C"

EPOGEN and PROCRIT

John Philo jphilo at amgen.com
Mon Nov 11 11:46:51 EST 1996

- Previous message: EPOGEN and PROCRIT
- Next message: Need help urgently !!!
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933467u at app_science.rgu.ac.uk wrote:

> *I understand that EPOGEN is given to dialysis patents and PROCRIT is*
> *given to people suffering from cancer and HIV / AIDS. Can anyone tell me*
> *if there's any difference between these drugs at the molecular level?*
>
> *As they're given to different classes of patient, I assume that they're*
> *different drugs? On the other hand it MIGHT be that due to some legal*
> *ruling, the manufacturers of the drugs (Amgen and Ortho Biotech) have*
> *been told to stick to seperate areas of the market. If this is the case,*
> *perhaps their products have different names simply to help people*
> *differentiate? In effect, one drug has been given two names???*

EPOGEN and PROCRIT are identical at the molecular level. Ortho provided financial support to Amgen for the development of erythropoietin as a therapeutic. In return, they obtained licensing rights to market the drug for all indications in the U.S. other than kidney dialysis.

In fact, fairly often hospital pharmacies only carry one of these two products, so PROCRIT can end up being used in dialysis patients or EPOGEN in AIDS patients. The two companies have a agreement on how to compensate each other for such "out of market" sales.

John Philo, Protein Chemistry
Amgen Inc., Thousand Oaks, CA
jphilo at amgen.com
*** Disclaimer: These are the opinions of the poster not Amgen Inc.***

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EXHIBIT "D"

Douglas F. Johnson, Esq.
EARP COHN P.C.
20 Brace Road, 4th Floor
Cherry Hill, NJ 08034
(856) 354-7700

Attorneys for Plaintiff
Ortho Biotech Products L.P.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORTHO BIOTECH PRODUCTS, L.P., Plaintiff, - v. - AMGEN INC., Defendant.	**Civil Action No. _____** **COMPLAINT AND JURY DEMAND**

Plaintiff Ortho Biotech Products, L.P. ("Ortho"), a New Jersey limited partnership with its principal place of business located at 430 Route 22 East, Bridgewater, NJ 08807, upon knowledge with respect to its own acts and upon information and belief with respect to all other matters, alleges by way of Complaint against Defendant Amgen Inc. ("Amgen"), a Delaware corporation with its principal place of business located at One Amgen Center Drive, Thousand Oaks, CA 91320, as follows:

SUMMARY OF CLAIMS

1. This antitrust action, brought under Sections 1 and 2 of the Sherman Act, involves an anti-competitive tying arrangement and pricing scheme

implemented by defendant Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell Growth Factor ("RBCGF") drug to its dominant White Blood Cell Growth Factor ("WBCGF") drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen's scheme is to monopolize the market for sales of RBCGF drugs to oncology clinics. The result will be less competition, less physician and patient choice and an increased expense to the public health system.

2. Ortho sells Procrit®. Amgen sells Aranesp®. Both are RBCGF drugs that compete head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products are projected to exceed $2.8 billion in 2005.

3. Amgen also sells Neulasta® and Neupogen®, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. Ortho does not sell a WBCGF drug.

4. Aranesp now accounts for roughly 66% of RBCGF drug sales to oncology clinics. Aranesp's share has increased by 46% over the past 18 months as the result of Amgen's illegal pricing practices that penalize oncology clinics on purchases of its monopoly WBCGF drugs, when those clinics do not agree to purchase significant volumes of its Aranesp, instead of Procrit.

5. On October 1, 2005, Amgen's pricing scheme became considerably more coercive. Amgen has now imposed even steeper pricing penalties on Amgen's monopoly WBCGF drugs when oncology clinics do not purchase up to 75% of their RBCGF drugs from Amgen. In fact, if a clinic wishes to continue to receive the

same level of rebates it had been receiving under the pre-October 1, 2005 contract, the clinic must increase its Aranesp share up to 90%.

6. Amgen's pricing scheme has reached the point where, for a substantial percentage of its patients, an oncology clinic is put in a completely untenable position. A clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government reimbursement. The clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when they purchase virtually all of their RBCGF drug requirements from Amgen.

7. Defendant's conduct constitutes a tying arrangement in violation of Section 1 of the Sherman Act under either a *per se* or Rule of Reason analysis. As the result of Amgen's monopoly power in the sale of WBCGF drugs to oncology clinics, Amgen's pricing scheme leaves oncology clinics with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. Moreover, WBCGF and RBCGF drugs are distinct and separate products and a not insubstantial amount of commerce is involved.

8. Amgen's actions also violate Section 2 of the Sherman Act. The purpose of Amgen's anticompetitive pricing scheme is to monopolize the oncology clinic market for RBCGF drugs in the United States in which Procrit is Amgen's only competitor. There is a dangerous probability that, by engaging in this exclusionary conduct, Amgen will succeed in its monopolistic plans.

9. The anticompetitive conduct at issue here will irreparably harm Ortho and is not in the public interest. If Amgen is not blocked from pursuing this new

pricing scheme, Procrit's ability to compete in the oncology clinic market for RBCGF drugs largely will cease. Since Procrit was introduced in 1991, it has been used to treat millions of patients who suffer from chemotherapy-induced anemia ("chemo-induced anemia"). Procrit was the first RBCGF drug on the market and it improved the lives of millions of patients. Ortho is viewed by thought leaders in the oncology market as one of the pioneers in addressing the needs of cancer patients undergoing chemotherapy. As a result, Ortho has longstanding relationships with oncology clinics and has built-up enormous goodwill in the Procrit brand.

10. Moreover, denying clinics and ultimately patients' access to Procrit is not in the public interest and will harm consumers. Physicians should not face economic coercion. Forcing physicians who treat cancer patients to abandon Procrit as the only economically viable way to gain access to another badly needed drug for their patients, is not, by any measure, in the public interest.

11. For these reasons and to remedy the injuries that will be caused and have been caused by Amgen's anticompetitive conduct, Ortho seeks a preliminary and permanent injunction as well as treble damages.

JURISDICTION AND VENUE

12. This complaint is filed under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1 and 2, and for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202.

13. Defendant transacts business and is found in this district. Substantial interstate trade and commerce involved and affected by the alleged violations of antitrust law occurs within this district. The acts complained of have had, and will have, substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22 and 26, particularly as plaintiff Ortho resides here.

THE PARTIES

14. Plaintiff Ortho is a limited partnership organized and existing under the laws of New Jersey with its principal place of business located in Bridgewater, New Jersey. Ortho is one of the Johnson & Johnson family of companies. Johnson & Johnson is a corporation with its principal place of business in New Brunswick, New Jersey. Ortho sells Procrit, the drug that is the target of Amgen's monopolistic schemes.

15. Defendant Amgen is a corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

FACTUAL ALLEGATIONS

A. Ortho and Amgen are the Only Competitors in the Sale of RBCGF Drugs to Oncology Clinics.

Procrit

16. Severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red

blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

17. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

18. Ortho sells Procrit®, a branded version of epoetin alfa. By Product License Agreement ("PLA") executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen®.

19. At the time of the PLA, the use of epoetin alfa to combat dialysis-induced anemia offered the greatest possibility for commercial success. However, there was no firm basis for predicting the viability of using epoetin alfa to treat anemia resulting from other disease states. Through costly research and clinical trials, Ortho demonstrated the efficacy of epoetin alfa to treat and reduce the need for transfusions in patients undergoing treatment for other diseases. Based upon this work, Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

20. Since Procrit was launched in 1991, it has been prescribed to millions who suffer from anemia included in the four indications listed above and became the standard of care for the treatment of chemo-induced anemia. As a result of Procrit's success, Ortho has paid Amgen over $1.5 billion in royalties on Procrit sales.

Aranesp

21. Amgen decided to circumvent the market exclusivity it had granted to Ortho to sell epoeitin alfa for all purposes other than dialysis. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

22. Ortho's work and investment in Procrit, which demonstrated that RBCGF drugs could be safely, effectively and widely used to combat chemo-induced anemia, helped Amgen to secure FDA approval of Aranesp and to sell Aranesp into markets in which physicians had been educated by Ortho about the benefits of RBCGF drugs.

23. Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp are projected to exceed $2.8 billion in 2005.

B. Amgen Has a Monopoly on the Sale WBCGF Drugs.

24. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially life threatening. Neutropenia is a side effect of chemotherapy which potentially

compromises a patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

25. Ortho does not sell a WBCGF drug, but Amgen does. Amgen sells two WBCGF drugs, Neupogen® and Neulasta®. The only other WBCGF drug sold is Leukine®, which is distributed by Berlex Laboratories.

26. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that one injection of Neulasta is roughly equal to 7 injections of Neupogen.

27. Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales. Unlike Amgen's WBCGF drugs which are administered by subcutaneous injection, Leukine must be administered intravenously – a longer and more costly process.

C. Amgen Seeks to Monopolize the Sales of RBCGF Drugs to Oncology Clinics by Leveraging its WBCGF Drug Monopoly.

1. Amgen Begins Bundled Pricing on Aranesp and its WBCGF Monopoly Drugs.

28. Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen.

29. This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Almost from the outset, Amgen's strategy for selling Aranesp has been to penalize a clinic on the pricing of its dominant WBCGF drugs if the clinic did not purchase substantial

amounts of Aranesp, a product that has competition. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs or their relative merits.

2. **The Early 2004 Amgen Contract**

30. Amgen's penalties became even more coercive in the spring of 2004. At that time, Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC").

31. Amgen's pricing to oncology clinics under its APC is broken into three groups – large, medium and small accounts – based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that once reached allows the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic's APC represent a specific percentage requirement of market share based on a clinic's historical usage. Rebates are earned when Amgen's share of the clinic's estimated total APC purchases reach those levels.

32. For example, under the APCs in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater rebates – a 25% rebate on its Aranesp

purchases and a 25% rebate on its Amgen WBCGF drug purchases. An oncology clinic that did not meet its APCs volume requirements would only receive a minimal rebate or discount. (Examples of the rebate levels for APCs during this time frame are attached as Attachment A.)

3. **The Late 2004 Amgen Contract**

33. Later in 2004, Amgen modified its APCs. Amgen apparently recognized that simply providing an oncology clinic with a combined dollar volume target might give the clinic the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

34. Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

35. Under the modification to the APCs in late 2004, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30.0% rebate on its Aranesp purchases and a 25.0% rebate on its WBCGF drug

purchases. (Examples of the rebate levels for APCs during this time frame are attached as Attachment B.)

36. All of these changes forced a clinic to buy less Procrit and more Aranesp in order for the clinic to get access to both the WBCGF and RBCGF rebates.

37. As a result of these pricing schemes, Ortho's share of sales to oncology clinics has dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. At present, Ortho's share is estimated to be approximately 34%, with Aranesp having a 66% share.

38. This significant shift in relative market share is attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

39. The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to oncology clinics with their respective share of sales in another market – sales to retail drug stores – where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores remains at approximately 70%.

D. Amgen's New Pricing Scheme is Designed to Eliminate Procrit from the Oncology Clinic Market.

40. Having gained a 65% share of sales to oncology clinics by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen has now sought to tighten its squeeze on this market. Effective October 1, 2005, Amgen's pricing scheme became significantly more coercive.

41. As with the old pricing scheme, each clinic is given a series of levels of dollar volume targets for its total Amgen purchases of RBCGF and WBCGF drugs, as illustrated below for a large account[1]. The higher the Amgen gross purchases the higher level of rebate an oncology clinic can achieve:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

42. However, to gain access to even the lowest rebate level described above an oncology clinic must now meet separate Aranesp and Neulasta dollar volume triggers. To avoid being penalized on its purchases of Amgen's dominant WBCGF drugs, the dollar volume for Aranesp purchases that an oncology clinic must achieve is now based on up to 75% of the oncology clinic's total RBCGF product purchases being Aranesp, i.e., a 75% market share.

43. A higher initial dollar volume threshold for Aranesp is only the start of this latest tying scheme. The true purpose of the new pricing scheme is to require oncology clinics to make Aranesp more than 75% of their RBCGF purchases. Under the modified APCs, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1st APC (described above), each clinic now must reach higher dollar volume (i.e., market share) levels of Aranesp. For example, for a large clinic, the top

[1] Examples for medium and small accounts are set forth in Attachment C.

Aranesp rebate is now 26%. This is 4% less than under the previous Amgen bundle of 30%. However, the clinic can earn back the additional 4% by taking its Aranesp share up to 90% as well as ensuring that Neulasta represents 90% of its WBCGF drug purchases. Thus, this new pricing scheme is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

44. The new pricing scheme also reduces the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases are of Amgen's Neulasta and the higher threshold for Amgen's Aranesp (up to 90%) is met.

45. The October 2005 addendum to the APC continues to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC does not place caps on Aranesp. This further drives oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen.

46. A clinic that does not meet its Aranesp volume requirement will only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is now being penalized an additional 3.1% to 5.5% on its Neulasta purchases.

E. The Impact of this Pricing Scheme on an Oncology Clinic's Medicare Business.

47. Failing to achieve a dollar volume of purchases of Aranesp roughly equivalent to a 75% market share will have severe economic consequences on an oncology clinic. Because the use of WBCGF drugs is the standard of care to treat neutropenia, oncology clinics have no choice but to carry Neulasta.

48. Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula an oncology clinic would have to pay Amgen hundreds of dollars more on each treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

49. On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The new formula is based on the drugs' average selling price ("ASP" as it is known in the industry) plus 6%. Thus, if a clinic bought a drug that had an ASP of $1,000, the clinic would be reimbursed $1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

50. As the term suggests, the ASP of a drug is an average based on the prices paid – and discounts and rebates earned – by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or can not, – avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

51. Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is $2,603.00. The Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta currently is $2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or $524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, a clinic must receive rebates and discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APCs. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen $295.87 more per administration of Neulasta than the clinic is being reimbursed by the government.

52. The foregoing example is based on Neulasta's existing list price. Reportedly, Amgen is in the process of increasing the list price of Neulasta. A list price increase will result in an oncology clinic losing even more money.

53. Amgen's latest pricing scheme will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp that translate into substantial market share requirements. This will create a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked. Few oncology clinics will be able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic which wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully manage and monitor

relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most are in no position to take such risks.

54. Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. Ortho understands that one Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme. Amgen already has nearly 65% of RBCGF drug sales in the oncology clinic market. The large scale conversion of existing Procrit accounts will effectively eliminate physician and consumer choice, as Procrit is driven out of the oncology clinic market.

F. Ortho's Ability to Respond Competitively is Constrained by Amgen's Tying Arrangement.

55. Ortho is an equally efficient competitor, and Ortho supports price competition between rival companies as the hallmark of a free market. Ortho is prepared and willing to engage in fair, head-to-head, price competition between Procrit and Aranesp. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts. That will only result in Ortho inevitably pricing below cost and in less competition.

56. As alleged in paragraph 49, the government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price competition between Aranesp and Procrit (in the form of discounts or rebates) would result in

Aranesp and Procrit each having a lower ASP as the government recalculates product ASPs. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, are not, and will not be, considered as the Aranesp ASP is recalculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, i.e., 6% of a lower ASP).

57. Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen is forcing Ortho to absorb on its one product the "discounts" Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it will drive the Procrit ASP down and correspondingly the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly.

58. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie – puts Ortho at an enormous disadvantage and effectively precludes price competition. If Ortho offers a discount on Procrit commensurate with discounts offered by Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit will be recalculated by the government at subsequent reporting intervals. (ASPs are recalculated each quarter based on pricing data from two quarters earlier.) Procrit will then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (i.e., 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen will not on Aranesp. Amgen's rebates are tied in large measure to its WBCGF drugs. Consequently, the

Aranesp ASP will not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp will force Ortho to continue to chase Procrit's ASP down – each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP remains stable because Amgen's WBCGF rebates will not affect the Aranesp ASP, although they are tied to and driving Aranesp sales. The Procrit price spiral will result in Ortho pricing Procrit below cost in order to match the Amgen's rebates on its WBCGF and RBCGF drugs.

59. It is anticipated that on January 1, 2006, the government will move hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 8%. The adoption of an ASP reimbursement system in hospitals will allow Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose competition in the sale of RBCGF drugs to oncology clinics. Amgen will again simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP.

G. Procrit is a Highly Effective Drug.

60. Procrit was the subject of extensive clinical trials demonstrating its effectiveness in the treatment of anemia and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy.

61. In May 2005, the results of a comparative clinical trial involving Aranesp and Procrit designed specifically to measure the rate of hemoglobin improvement were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). The study authors, led by Dr. Roger Waltzman of Saint Vincent's Comprehensive Cancer Center, concluded (1) a trend toward a lower rate of transfusion in Procrit-treated patients when

compared to Aranesp-treated patients, and (2) a significant difference between treatments in the total number of red blood cell units transfused, with Procrit-treated patients requiring far fewer units per patient transfused than Aranesp treated patients.

62. Aside from the expense, time and invasive nature of the procedure, transfusions present numerous medical risks. Chemotherapy patients are significantly benefited by a reduction in the number of transfusions and the amount of blood transfused, as is the health care system as a whole since the available blood supply for emergency use in other patients is not otherwise depleted.

63. Also, in May 2005 at the ASCO meeting, there was a presentation on a comparative study of Procrit and Aranesp sponsored by Amgen and led by Dr. John Glaspy of the University of California at Los Angeles. The study was designed to find "non-inferiority" of either product if the level of transfusions fell within a broad range. Having defined equivalence in these broad terms, the study concluded that Procrit and Aranesp were not inferior to one another.

64. Finally, at the May 2005 meeting, there was a presentation based on an independent, retrospective chart review conducted by Dr. A.S. Case with the University of Alabama at Birmingham. The review was directed at determining the transfusion rates after treatment with Procrit and Aranesp. Based on this observational data, the authors found that a significantly lower proportion of patients required transfusions, and fewer total units were transfused, when treated with Procrit rather than Aranesp.

H. Amgen's Pricing Schemes Injure Competition.

65. Amgen's pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces oncology clinics to purchase its RBCGF product, Aranesp, as a condition for receiving

substantial price rebates on products that they must purchase from Amgen – WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, oncology clinics will not qualify for the massive rebates provided on Amgen's dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, oncology clinics are given even higher rebates. The only economically viable option for these oncology clinics is to purchase all or nearly all of their RBCGF drugs from Amgen, even though many physicians would prefer Procrit if Aranesp competed head-to-head with Procrit.

66. Amgen's actions substantially foreclose Ortho from selling Procrit to oncology clinics. This foreclosure is demonstrated by the significant market share shift that has occurred and will continue to occur as Amgen ratchets up its leverage by implementing its latest pricing scheme.

67. This anticompetitive foreclosure has caused Ortho to lose revenue and profits that it otherwise would have earned, disrupted Ortho's relationships with Oncology clinics, resulted in loss of good will and other harm to Ortho's ability to innovate and compete.

68. The anti-competitive effects of Amgen's tying and attempts to monopolize extend far beyond the substantial foreclosure of Ortho, which is Amgen's only competitor in the sale of RBCGF drugs. There are numerous other potential uses for epoetin alfa that will likely develop in free and competitive drug markets. Without achieving a reasonable rate of return on current uses of Procrit, the ability of Ortho to fund current and future research and development projects related to alternative uses of Procrit and to seek regulatory approvals for these alternative uses is substantially

reduced. Ortho's ability to enter new markets with Procrit, either as a first mover or as a challenger to incumbents, is severely undermined by Amgen's tying and attempt to monopolize.

69. Amgen's tying arrangement would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will cause anticompetitive effects by increasing the barriers to entry into RBCGF drug markets.

70. In addition, Amgen's conduct enhances and reinforces its monopoly power in the market for WBCGF drugs.

I. Amgen's New Pricing Scheme Will Irreparably Harm Ortho and the Public.

71. Amgen's latest pricing scheme is intended to foreclose Ortho from a sizeable segment of the oncology clinic market, and will embolden Amgen to take similar action in the hospital market. This development will have a devastating impact on Ortho and on patient care. Ortho will lose important longstanding customer relationships as well as the goodwill built up over the years of the Procrit franchise which has been used to treat millions of cancer patients suffering from the severe anemia that often accompanies chemotherapy. Amgen's actions will likely result in reductions in investments in ongoing research and development in order to provide better forms of treatment.

72. Eliminating Ortho as an effective competitor in the oncology clinic market will also result in less physician choice. Physicians and patients should not be effectively cut off from access to the benefits of Procrit—which many physicians would

prefer to Aranesp by virtue of Amgen's use of its monopoly leverage in the sale of WBCGF drugs.

73. If Amgen is permitted to implement its latest pricing scheme into the oncology clinic market, with the success that is envisioned and is economically predictable, Amgen will simply do the same thing in the hospital market when hospitals are reimbursed under an ASP system in January of 2006. This will compound the irreparable harm to Ortho and physicians and patients.

J. There is No Legitimate Business Justification for Amgen's Tying Arrangement.

74. There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating Ortho and potential entrants as competitors in the sale of RBCGF drugs to oncology clinics.

K. Sales of RBCGF Drugs to Oncology Clinics Constitute a Relevant Product Market.

75. RBCGF drugs are sold through various channels. The roughly 2,400 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over $2.8 billion in gross sales projected in 2005. "Oncology clinics" include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

76. To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive out-patient administration of RBCGF drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

77. Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with non-dialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

78. Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of Ortho's Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

79. An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than do hospitals.

80. Hospitals cannot buy more RBCGF drugs than they need and "arbitrage" a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit.

81. Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the government are different than what are used for other industry participants, such as hospitals.

82. Most oncology clinics purchase drugs through entities called "specialty distributors." Specialty distributors deliver oncology drugs, which often require careful handling (e.g., refrigeration), to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics.

83. Oncology clinics have formed their own Group Purchasing Organizations ("GPO") to negotiate with drug manufacturers. Historically, certain purchasers of pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs. Hospitals, for instance, belong to GPOs. These hospital GPOs generally do not permit oncology clinics to participate. In recent years, oncology clinics began to form specialized GPOs in an effort to achieve lower prices.

84. The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

85. There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen's exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, and (2) secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

L. Sales of WBCGF Drugs to Oncology Clinic Constitute a Distinct and Separate Product Market.

86. The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.

87. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

88. Recognizing this, the Federal Trade Commission ("FTC") stated that "the research, development, manufacture and sale of Neutrophil Regeneration Products" (a.k.a. WBCGF drugs) is a "relevant line of commerce" in a Clayton Act §7 administrative Complaint filed against Amgen and the Immunex Corporation.

89. The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

90. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

(Per Se and Rule of Reason Unlawful Tying)

91. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 90 with the same force and effect as if here set forth in full.

92. Amgen has engaged in an unlawful contract, combination, conspiracy and agreement in unreasonable restraint of trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. §1. This includes agreements with oncology clinics that force them to purchase all or nearly all of their demand for RBCGF drugs from Amgen.

93. The product characteristics, uses and character of demand for RBCGF drugs -- which are used to treat chemotherapy-induced anemia but not neutropenia -- are different from the product characteristics, uses and the character of demand for WBCGF drugs -- products that treat neutropenia, but not anemia. RBCGF and WBCGF drugs are distinct products: they are used to treat different conditions and are not functionally interchangeable.

94. At all times relevant to this action, Amgen has had market power in the sale of WBCGF drugs sufficient to force oncology clinics that purchase WBCGF drugs to also purchase Aranesp regardless of whether these purchasers actually preferred Procrit.

95. A substantial amount of interstate commerce has been and is being affected by Amgen's tying arrangement. The total purchases of RBCGF drugs by oncology clinics in 2005 is projected to exceed $2.8 billion in gross sales.

96. Amgen's tying arrangement forces oncology clinics to purchase all or nearly all of their demand for RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's pricing schemes, which offer significant rebates for the purchase of Amgen's dominant WBCGF drugs if they are purchased in a package with large quantities of Aranesp, the only economically viable option for oncology clinics that need WBCGF drugs is increasingly for them to purchase all or nearly all of their RBCGF drugs from Amgen.

97. Amgen's tying arrangement has substantially foreclosed and will continue to substantially foreclose Ortho from competing with Amgen for the sale of RBCGF drugs to oncology clinics based on the efficacy of its product and the price of its

product on a stand-alone basis. Amgen's pricing scheme has reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit for patients who suffer from ailments or diseases not currently treated by Epoetin Alfa.

98. Amgen's tying arrangement has no legitimate business purpose. It achieves no legitimate efficiency benefits and has the anticompetitive effect of foreclosing competition on the merits for the sale of RBCGF drugs to oncology clinics.

99. Amgen's tying arrangement has adversely effected competition in the sale of RBCGF drugs to oncology clinics and will continue to do so unless enjoined.

100. As a result of Amgen's violations of Section 1 of the Sherman Act, Ortho has been injured in its business and property in an amount not presently known, but which is, at a minimum, in excess of one millions dollars, prior to trebling.

101. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

SECOND CLAIM FOR RELIEF

(Attempt to Monopolize RBCGF Drug Market)

102. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 100 with the same force and effect as if here set forth in full.

103. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Amgen has willingly, knowingly, intentionally and with specific intent to do so, attempted to monopolize sales of RBCGF drugs to oncology clinics.

104. This attempt to monopolize has been effectuated by a variety of unlawful conduct undertaken with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:

- conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from defendant;
- granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and
- entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from defendant.

105. There is a dangerous probability that Amgen, by using these exclusionary practices, will monopolize the sale of RBCGF drugs to oncology clinics.

106. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to oncology clinics. Amgen's conduct has substantially foreclosed and will continue to substantially foreclose competition on the merits from Ortho in the sale of RBCGF drugs to oncology clinics and other customers. Amgen's conduct will also raise barriers to entry for potential competitors for the sale of RBCGF and WBCGF drugs. Amgen's conduct has also reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit to benefit patients who suffer from ailments or diseases not currently treated with Epoetin Alfa.

107. Amgen intends to take further acts aimed specifically at further foreclosing competition in the sale of RBCGF drugs to oncology clinics.

108. There is no legitimate business justification or pro-competitive benefit from Amgen's exclusionary practices.

109. As a result of Amgen's violations of Section 2, Ortho has been injured in its business and property in an amount not presently known but which is, at a minimum, in excess of one millions dollars prior to trebling.

110. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Ortho Biotech Products, L.P. respectfully requests the following relief:

A. That the Court declare, adjudge and decree that Defendant Amgen Inc. has committed the violations of federal law alleged herein;

B. That the Court enter a preliminary and permanent injunction enjoining Amgen Inc. from employing its latest pricing scheme, which began effective October 1, 2005, and any comparable pricing scheme that achieves the same result of coercing oncology clinics to purchase substantial amounts of Aranesp as a condition of access to substantial discounts on Amgen's WBCGF drugs;

C. That Amgen Inc., its directors, officers, employees, agents, successors, and assigns be permanently enjoined and restrained from, in any manner, directly or indirectly conditioning the sale or discounts on the sale of WBCGF drugs on the purchase of RBCGF drugs or any other conduct which has the same purpose or effect, and committing any other violations of Sections 1 and 2 of the Sherman Act described herein and that Amgen, its directors, officers, employees, agents, successors and assigns be enjoined and restrained from, in any manner, directly or indirectly, committing any other violations of the antitrust laws or statutes having a similar purpose or effect; and

D. That the Court award to Plaintiff Ortho Biotech Products, L.P. the damages it has sustained as a result of the illegal conduct of Defendant Amgen Inc., in an amount to be proved at trial, to be trebled according to law, plus interest (including prejudgment interest), attorneys' fees and costs of suit, and such other and further relief as this Court may deem just and proper.

JURY DEMAND

Ortho hereby demands trial by jury of all issues properly triable thereby.

Dated: Trenton, New Jersey
October 11, 2005

By: _____
Douglas F. Johnson

EARP COHN P.C.
20 Brace Road, 4th Floor
Cherry Hill, NJ 08034
(856) 354-7700
(856) 354-0766 Facsimile

PATTERSON BELKNAP WEBB & TYLER LLP
William F. Cavanaugh, Jr.
Erik Haas
Jeffrey D. Rotenberg
Wendy Kemp Akbar
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000
(212) 336-2222 Facsimile

and

CONSTANTINE CANNON PC
Lloyd Constantine
Matthew L. Cantor
Reiko Cyr
Axel Bernabe
450 Lexington Avenue
New York, New York 10017
(212) 350-2700
(212) 350-2701 Facsimile

Attorneys for Plaintiff
Ortho Biotech Products, L.P.

ATTACHMENT A

Large Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	25.00%	25.00%
	80%	20.00%	20.00%
	75%	18.50%	13.50%
	70%	14.5%	11.50%
	65%	13.5%	10.50%
	55%	11.5%	7.5%
	50%	5%	5%

Medium Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	20.00%	21.00%
	80%	18.00%	16.00%
	75%	16.50%	12.50%
	70%	13.5%	10.50%
	65%	12.5%	9.50%
	55%	10.5%	6.5%
	50%	4%	4%

Small Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	16.00%	16.00%
	80%	14.00%	14.00%
	75%	12.00%	11.50%
	70%	11.00%	9.50%
	65%	10.00%	8.50%
	55%	8.50%	5.50%
	50%	3%	3%

ATTACHMENT B

Large Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	30.00%	25.00%
	80%	25.00%	20.00%
	75%	23.50%	13.50%
	70%	19.5%	11.50%
	65%	18.5%	10.50%
	55%	11.5%	7.5%
	50%	5%	5%

Medium Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	25.00%	21.00%
	80%	23.00%	16.00%
	75%	21.50%	12.50%
	70%	18.5%	10.50%
	65%	17.5%	9.50%
	55%	10.5%	6.5%
	50%	4%	4%

Small Account:

Tier – combined		Rebate	
	Share of RBCGF and WBCGF Drugs	Aranesp	Neupogen/Neulasta
	85%	21.00%	16.00%
	80%	19.00%	14.00%
	75%	17.00%	11.50%
	70%	16.00%	9.50%
	65%	15.00%	8.50%
	55%	8.50%	5.50%
	50%	3%	3%

ATTACHMENT C

Medium Account:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	21.0%	17.0%	16.0%
5	20.5%	16.5%	15.0%
4	20.0%	16.0%	14.0%
3	19.5%	15.5%	13.0%
2	19.0%	15.0%	12.0%
1	18.5%	14.5%	11.0%
base level	18.0%	14.0%	10.0%

Small Account:

	Rebates		
	Aranesp®	Neulasta®	Neupogen®
Level of Amgen Purchases			
6	18.00%	12.00%	11.00%
5	17.50%	11.50%	10.00%
4	17.00%	11.00%	9.00%
3	16.50%	10.50%	8.00%
2	16.00%	10.00%	7.00%
1	15.50%	9.50%	6.00%
base level	15.00%	9.00%	5.00%

EXHIBIT "E"

[FILED UNDER SEAL]

EXHIBIT "F"

[FILED UNDER SEAL]

EXHIBIT "G"

00001

HIGHLY CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER
* * *
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

- - - - - - - - - - - - - - - - x
IN RE PHARMACEUTICAL INDUSTRY :
AVERAGE WHOLESALE PRICE : CIVIL ACTION:
LITIGATION : 01-CV-12257-PBS
- - - - - - - - - - - - - - - - x

Mt. Crested Butte, Colorado
Friday, August 12, 2005

Videotaped Deposition of CAROL WEBB, a witness herein, called for examination by counsel for Plaintiffs in the above-entitled matter, pursuant to notice and the Federal Rules of Civil Procedure, the witness being duly sworn by CRAIG KNOWLES, a Notary Public in and for the State of Colorado, at 9:30 a.m., and the proceedings being taken down in Stenotype by CRAIG KNOWLES and transcribed under his direction.

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APPEARANCES:

On behalf of the Plaintiffs:
ALLAN M. HOFFMAN, ESQ.
Hoffman & Edelson, LLC
45 West Court Street
Doylestown, Pennsylvania 18901
Ph. (215) 230-8043
Fax (215) 230-8735

On behalf of Johnson & Johnson and its Operating Companies and Carol Webb:
ADEEL A. MANGI, ESQ.
Patterson, Belknap, Webb & Tyler, LLP
1133 Avenue of the Americas
New York, New York 10036-6710
Ph. (212) 336-2563
Fax (212) 336-7947

ALSO PRESENT: Kenneth Zoetewey, Videographer

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know what that is referring to?
A. No. I mean, it's very general here.
Q. Okay. And how about spillover sales?
MR. MANGI: Objection.
A. It's also general.
BY MR. HOFFMAN:
Q. What is it you are referring to when he says spillover sales?
A. Spillover sales is, in a contractual agreement with Amgen, what spillover sales mean is that there was an audit in place and that would measure the usage of Epogen in our indicated areas or the use of Procrit in their indicated areas.
Q. And that was for unintended sales into each other's areas?
A. That's correct.
Q. So you would agree that OBI was -- OBI management knew that customers were using Epogen in the non-dialysis sector as a competing drug?
MR. MANGI: Objection. Lack of foundation and form.
A. You are making some assumptions there, so I

00150

A. That's correct.
MR. MANGI: Objection. Lack of foundation.
BY MR. HOFFMAN:
Q. You had said I had made some faulty assumptions or assumptions.
In fact, isn't it true management knew there were sales going into each other's sector? Management of OBI knew that --
A. Based on what?
Q. Based on the fact that they were willing to enter into an agreement and based on the audit.
A. Entering into what kind of agreement?
Q. I don't have to -- let me just --
MR. MANGI: You do have to clarify your question.
MR. HOFFMAN: I don't have to go down that road, is what I am saying.
BY MR. HOFFMAN:
Q. Did the audit show at any time that sales were spilling over into -- sales of Epogen were spilling over into the non-dialysis sector?
A. Yes.

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BY MR. HOFFMAN:

Q. Was there any dual use that was using Epogen as opposed to Procrit?

MR. MANGI: Objection. The question is incomprehensible as stated.

MR. HOFFMAN: I understand the objection.

BY MR. HOFFMAN:

Q. Was there any customer that had a dual use, a dual use facility that used epoetin alfa that told you in any communication or that you heard from someone else at OBI that they considered the two drugs to be competing and interchangeable?

A. Interchangeable, but not competing.

Q. Okay. Were you aware that dual use customers were using Epogen in the non-dialysis sector?

A. Yes.

Q. But you don't consider that to be a perception that they were competing?

A. No.

Q. Okay. What in your eyes would require you to reach the conclusion that in fact customers did

EXHIBIT "H"

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Magistrate Judge Marianne Bowler
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	

DECLARATION OF MARK E. DUXBURY

I, Mark Eugene Duxbury, declare as follows:

1. My name is Mark Eugene Duxbury.

2. The statements in this declaration are made upon my personal knowledge of information and events.

3. I was employed by Ortho Biotech Products, LLP ("OBI") from February 1992 through July 1998.

4. Initially, I was employed as an OBI Product Specialist and later became an OBI Key Account Specialist.

5. In both positions, I was responsible for the promotion of Procrit in the Northwestern Region of the United States.

6. When I started working at OBI, I learned that Amgen and OBI had entered into a Product License Agreement ("PLA") whereby Amgen licensed to OBI the right to

sell the Procrit® brand of Epoetin alfa for non-dialysis use in the United States and retained the right to sell the Epogen® brand of Epoetin alfa for dialysis use.

7. In 1992, I was selling Procrit to the vast majority of the non-dialysis market in my territory, which amounted to approximately $250,000 for the year.

8. It soon became obvious to me that, for all practical purposes, a significant non-dialysis market did not exist.

9. In early 1993, I was given a sales quota of $1.1 million, which was raised in mid-1993 to $1.6 million, neither of which I could meet without converting large Epogen dialysis accounts to Procrit. After meeting my 1993 quota, my 1994 quota was raised to $3.2 million, despite the fact that OBI management had strong evidence that my quotas were based on Dialysis business.

10. Epoetin alfa was the ultimate commodity because Epogen and Procrit were the identical substance and provided the same clinical benefits, and were reimbursed at the same or virtually the same amount in the dialysis and non-dialysis sectors. Therefore, to persuade customers to switch from Epogen to Procrit, OBI sales representatives, including myself, with the knowledge and approval of my superiors, promoted the clinical benefits and greater profit and margin available to the customer from Procrit based on the difference between acquisition cost and reimbursement.

11. I was very successful at converting Epogen dialysis business to Procrit, and received OBI awards for my productivity, including Ortho's Biosphere Award in 1993 and 1994, which is annually awarded to the top 10% of OBI's sales force.

12. In 1994, I was responsible for 40% of the Procrit sales growth in the Northwest Region, virtually all of which was the result of converting Epogen dialysis business to Procrit.

13. This was achieved by offering steep discounts (up to 14%), rebates and soft money in the form of unrestricted educational grants from OBI to hospitals and dialysis centers to lower their acquisition cost for Procrit below that of Epogen and thus create a greater profit margin from reimbursement.

14. For example, in the early days of the battle for market share, OBI conducted "fire sales" which offered steep discounts to large volume dialysis customers to create a larger spread between acquisition cost and reimbursement for Procrit.

15. Procrit purchasers in dialysis and/or non-dialysis areas knew that Medicare reimbursed for Epoetin alfa because it was generally their largest line item expense and they had no difficulty subtracting the purchase price from the reimbursement rate to figure out their profit margin. Per my training, I also instructed my accounts that, even with the lower purchase price, the amount of reimbursement that they would receive would not change.

16. OBI instructed its sales representatives that after offering a lower price to customers, to ask whether the price differential was enough to motivate the purchaser to switch from Epogen to Procrit.

17. I promoted Procrit in the same manner regardless of whether a customer was reimbursed under Medicare and private payers, or reimbursed solely under Medicare.

18. One of my greatest successes was the conversion of St. Joseph's Hospital in Tacoma, Washington from Epogen to Procrit.

19. With the knowledge of OBI management, I promoted Procrit to St. Joseph's at discounted prices considerably lower than the prices St. Joseph's was paying for Epogen.

20. As a promotional incentive to motivate St. Joseph's to purchase Procrit for its dialysis use, I also arranged, with OBI's management's knowledge and approval, to provide an unrestricted $10,000.00 grant to be paid to St. Joseph's Hospital, which was hand delivered by me to Robert Dimino, the dialysis pharmacist at St. Joseph's. Six months later, an unrestricted educational grant of $20,000 was paid to St. Joseph's to reward them for their $500,000 in purchases since their conversion to Procrit.

21. I received OBI's Regional Achievement Award for the St. Joseph's conversion of Epogen to Procrit.

22. Although there are not as many freestanding dialysis centers in the Northwestern Region of the United States as in other parts of the country, I did promote Procrit to freestanding dialysis centers when directed to do so by OBI management.

23. One such facility located in my territory was the Mid-Columbia Kidney Center operated by Dr. John L. Boykin in Richland, Washington.

24. I provided Dr. Boykin with a promotional flyer for Procrit created by Charise Charles Ltd., Inc. ("Charise"), which provided lower pricing on Procrit brand than could be found from other distributors for Epogen brand.

25. Charise received discounts from OBI that were more favorable than those provided to other wholesalers and Charise passed a portion of its discount along to its customers.

26. In addition, Charise included the OBI 8% physician's rebate in its promotional pricing, along with Charise's own rebate.

27. I considered Charise to be an OBI surrogate.

28. During my career at OBI, there was no policy prohibiting the sales force from marketing or promoting Procrit to customers based on profit or margin that could be derived from the spread between reimbursement and acquisition cost.

29. In fact, the sales force was trained by OBI managers to talk about the financial, as well as clinical, advantages of Procrit.

30. My Regional Managers directed the whole Western Region, including me, to discuss the profit physicians and practices could earn from reimbursement during sales calls to oncology clinics.

31. I recently worked as a consultant for the law firm of Hagens Berman Sobol Shapiro for approximately two and a half years. During that time, I served as a consultant on various matters relating to the drug industry but did not work on the AWP case as it relates to the drug Procrit as I was a plaintiff in a qui tam action against OBI that was under seal.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 4-28-06

Mark E. Duxbury

EXHIBIT "I"

Untitled

[Federal Register: August 5, 2004 (Volume 69, Number 150)]
[Proposed Rules]
[Page 47487-47730]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr05au04-28]

[[Page 47487]]

Part II

Department of Health and Human Services

Centers for Medicare and Medicaid Services

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42 CFR Parts 405, 410, 411, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule

[[Page 47488]]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 418, 424, 484, and 486

[CMS-1429-P]
RIN 0938-AM90

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would refine the resource-based practice expense relative value units (RVUs) and make other changes to Medicare Part B payment policy. The proposed policy changes concern: supplemental survey data for practice expense, updated geographic practice cost indices for physician work and practice expense, updated malpractice RVUs, revised requirements for supervision of therapy assistants, revised payment rules for low osmolar contrast media, changes to payment policies for physicians and practitioners managing dialysis patients, clarification of care plan oversight requirements, revised requirements for supervision of diagnostic psychological testing services, clarifications to the policies affecting therapy services, revised requirements for assignment of Medicare claims, addition to the list of telehealth services, and several coding issues.

We are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. We solicit comments on these proposed policy changes.

This proposed rule also addresses the following provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA): coverage of an initial preventive physical examination; coverage of cardiovascular screening blood tests; coverage of diabetes screening tests; incentive payment improvements for physicians in shortage areas; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; coverage of routine costs associated with certain clinical trials of category A devices as defined by the Food and Drug Administration; hospice consultation service; indexing the Part B deductible to inflation; extension of coverage of intravenous immune globulin (IVIG) for the treatment in the home of primary immune deficiency diseases; revisions to reassignment provisions; clinical conditions for payment of covered items of durable medical equipment; and payment for diagnostic mammograms.

In addition, we discuss physicians' services associated with drug administration services and payment for set-up of portable x-ray equipment.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 24, 2004.

ADDRESSES: In commenting, please refer to file code CMS-1429-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific issues in this regulation to http://www.cms.hhs.gov/regulations/ecomments. (Attachments should be in Microsoft Word, WordPerfect, or

Excel; however, we prefer Microsoft Word.)

2. By mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1429-P, P.O. Box 8012, Baltimore, MD 21244-8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7197 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ``Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

Pam West (410) 786-2302 (for issues related to Practice Expense, Respiratory Therapy Coding, and Therapy Supervision).
Rick Ensor (410) 786-5617 (for issues related to Geographic Practice Cost Index (GPCI) and malpractice RVUs).
Craig Dobyski (410) 786-4584 (for issues related to list of telehealth services or payments for physicians and practitioners managing dialysis patients).
Bill Larson or Tiffany Sanders (410) 786-7176 (for issues related to coverage of an initial preventive physical examination).
Cathleen Scally (410) 786-5714 (for issues related to payment of an initial preventive physical examination).
Joyce Eng (410) 786-7176 (for issues related to coverage of cardiovascular screening tests).
Betty Shaw (410) 786-7176 (for issues related to coverage of diabetes screening tests).
Anita Greenberg (410) 786-0548 (for issues related to payment of cardiovascular and diabetes screening tests).
David Worgo (410) 786-5919, (for issues related to incentive payment improvements for physicians practicing in shortage areas).
Angela Mason or Jennifer Fan (410) 786-0548 (for issues related to payment for covered outpatient drugs and biologicals).
David Walczak (410) 786-4475 (for issues related to reassignment provisions).
Henry Richter (410) 786-4562 (for issues related to payments for ESRD facilities).
Steve Berkowitz (410) 786-7176 (for issues related to coverage of routine costs associated with certain clinical trials of category A devices).
Terri Deutsch (410) 786-9462 (for issues related to hospice consultation services).
Karen Daily (410) 786-7176 (for issues related to clinical conditions for payment of covered items of durable medical equipment).

****

percent for Urology, 97 percent for Rheumatology and 73 percent for Obstetrics/Gynecology. For drugs in which we did not complete our validation of the ASP submission before completing the proposed rule, we used the average payment change for other drugs provided by the specialty unless a special circumstance applied. (that is, for Hematology/Oncology and Obstetrics/Gynecology, we calculated the average reduction in payment for drugs excluding J9265, J2430, and J9390, three drugs having an unusually large reduction in payment as a result of coming off patent. We do not believe these reductions will be typical of other drugs furnished by oncologists and obstetrician/gynecologists).

Our estimates of changes in Medicare revenues for drugs and physician fee schedule services compare payment rates for 2005 with payment rates for 2004 using 2003 Medicare utilization for both years. We are using 2003 Medicare claims processed and paid through June 30, 2004 that we estimate are 96.7 complete and have adjusted the figures to reflect a full year of data. Thus, because we are using a single year of utilization, the estimated changes in revenues reflect payment changes only between 2004 and 2005. To the extent that there are year-to-year changes in the volume and mix of drugs and physician fee schedule services provided by physicians, the actual impact on total Medicare revenues will be different than those shown here.

Assuming no change in utilization, we estimate that Medicare drug revenues for oncologists would decline by less than 8 percent as a result of policies adopted in this proposed rule. Oncologists administer a number of drugs that are changing in payments by different amounts. For instance, oncologists' highest Medicare revenue drug, Q0136 (EPOGEN; PROCRIT), would decline in payment by 7 percent while its second highest revenue drug, J9310 (RITUXAN), would increase in payment by 7 percent. Three drugs supplied by oncologists, J9265 (ONXOL TAXOL), J2430 (PAMIDRONATE DISODIUM), and J9390 (NAVELBINE), are coming off patent and their price would decline respectively by 81 percent, 71 percent, and 12 percent. The 2004 Medicare payment amounts for these three drugs respectively were equal to 81, 85 and 81 percent of the April 1, 2003 average wholesale price levels that applied or did not decrease proportionally after the drugs came off patent. These three drugs are estimated to account for only 7 percent of oncologists adjusted 2004 Medicare drug revenues but contribute more than 5 percent of the approximate 8 percent total reduction in Medicare drug revenues that oncologists would experience as a result of adopting the ASP+6 payment methodology. While Medicare revenues to oncologists would decline from the reductions in payment for these three drugs, the cost to acquire these drugs has already declined. Thus, Medicare's payment, as with all other drugs experiencing payment changes, will be much closer to the cost the physician pays to acquire the drug.

Adoption of ASP+6 prices would reduce Medicare drug revenues for urologists by approximately 36 percent. This large reduction can be attributed to a 35 percent reduction in payment for two drugs: J9202 (ZOLADEX) and J9217 (LUPRON DEPOT-PED). While we estimate an even larger reduction in the ASP+6 price for J9217, our payment impact assumes that nearly all Medicare carriers are using the ``least costly alternative'' pricing and paying code J9217 at the J9202 price.

We estimate a 6 percent reduction in Medicare drug revenues for rheumatology. Nearly all of this reduction can be attributed to a 6 percent reduction in Medicare payment for J1745 (REMICADE).

We estimate less than an 18 percent decrease in Medicare drug revenues for obstetrics/gynecology. However, much of this revenue reduction can be attributed to an 81 percent reduction in payment for J9265 (ONXOL TAXOL) coming off patent. Even though this one drug is estimated to account for only 16 percent of obstetrics/gynecology

adjusted 2004 Medicare drug revenues, it contributes 13 percent of the approximate 18 percent total reduction in Medicare drug revenues that obstetrics/gynecologists would experience as a result of adopting the ASP+6 payment methodology. As explained above, while Medicare revenues to obstetrics/gynecology would decline as a result of the price reduction for this code, Medicare's payment will be much closer to the price physicians pay to acquire the drug. We are estimating an average approximate reduction of 6 percent across other drugs supplied by obstetrics/gynecology.

The remaining columns of Table 26 show the potential impact on physician fee schedule services of changes being contemplated for 2005 for the specialties shown. The column labeled ``Practice Expense and Malpractice RVU Changes'' show the combined impact of the changes previously illustrated for these specialties in Tables 21 and 22. The column labeled ``Drug Administration Payment Changes'' shows a range of potential physician fee schedule impacts for 2005. The left side of this column shows the impact of the changes required in payment by section 303(a)(4) of the MMA (that is, the change in the transition payment from 2004 to 2005) if we were to make no further changes to the payments or codes for drug administration services. However, because we are considering further changes to the payments or codes for drug administration once the AMA's CPT Panel review of this issue is complete, the right hand side of the column labeled ``Drug Administration Payment Changes'' reflects the amount that physician fee schedule payments would have to increase to make the net reduction across all Medicare revenues for these specialties equal to 2 percent. The next column shows the physician fee schedule update of 1.5 percent and the final column labeled ``Total Physician Fee Schedule'' Changes'' shows the combined effect of all of the changes previously described. The left hand side of the column shows the combined effect of (1) the practice expense and malpractice RVU changes, (2) the maximum reduction in payment that could occur if we made no further changes to payments for drug administration and (3) the physician fee schedule update. The right hand side of the column shows the combined effect of (1) the practice expense and malpractice RVU changes, (2) the amount physician fee schedule revenues would have to increase to make the reduction in total revenues equal to 2 percent and (3) the physician fee schedule update.

If we made no further changes to drug administration, physician fee schedule revenues would decline by 9 percent for oncology, be unchanged for urology and rheumatology, and increase by 1 percent for obstetrics/gynecology. Physician fee schedule revenues would have to increase by 12 percent for oncology, 19 percent for urology, 2 percent for rheumatology and 1 percent for obstetrics/gynecology for total revenues to these specialties to decline by 2 percent from adoption of the ASP+6 percent drug payment methodology.

Table 27 shows the combined impact of changes we are making to Medicare drug and physician fee schedule payments for the same specialties shown in table 26. The column labeled ``% of Total Medicare Revenues from Drugs'' shows the proportion of total Medicare revenues received from drugs, while the next column shows the payment impact from adoption of the ASP+6 drug payment methodology. The following columns show the proportion of total Medicare revenues received

EXHIBIT "J"

DOH Medicaid Update November 2005 Vol. 20, No. 12

Office of Medicaid Management
DOH Medicaid Update
November 2005 Vol. 20, No. 12

State of New York
George E. Pataki, Governor

Department of Health
Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner

Medicaid Update
is a monthly publication of the
New York State Department of Health,
Office of Medicaid Management
Kathryn Kuhmerker, Deputy Commissioner

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eMedNY Update All Providers!

Phase II Compliance Deadline December 31, 2005

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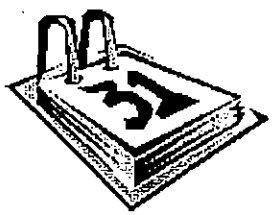
Since the end of our eMedNY transition period on June 20, 2005, the Department has permitted providers to continue to submit legacy two-digit locator codes and two-digit license type codes instead of the eMedNY required three-digit locator codes and three-digit profession codes. Also, providers have been able to continue entering an eight-digit Prior Authorization (PA) number where an eleven-digit number has been assigned. The purpose for the accommodation was to give providers still experiencing difficulties with the new eMedNY billing requirements additional time to complete their conversions.

Please be advised that the deadline for all providers to be fully compliant with the eMedNY Phase II requirements is December 31, 2005. This date is final!



Beginning January 1, 2006, eMedNY will **only** accept the three-digit *locator* codes, and license numbers must be preceded by three-digit *profession* codes. Claims submitted with the legacy two-digit locator code and/or two-digit license type code *will be rejected.* Eight-digit PA numbers will only be accepted where an eight-digit number was issued.

If you have not yet been able to convert your billing system to accommodate the Phase II required changes please expedite your efforts now. If you purchase software from a vendor or utilize services of a clearinghouse or a billing service you need to contact them immediately. Make sure they are aware of the eMedNY requirements and are proceeding aggressively with the changes.

Please do not place your Medicaid revenue stream at risk. Make sure you are completely compliant before December 31, 2005.

Questions? Contact CSC Provider Services at (800) 343-9000.

BILLING FOR EPOGEN, ARANESP, NEUPOGEN & NEULASTA

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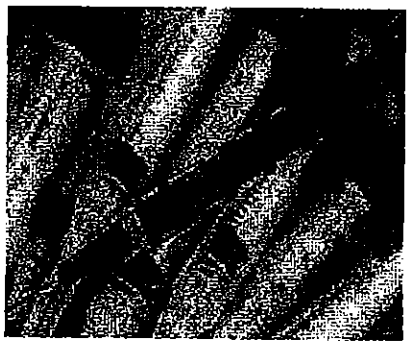

This provides clarification of proper procedure coding on claims for Epogen, Aranesp, Neupogen and Neulasta for **Categories of Service (COS)** listed below.

Medicaid as Sole Coverage

Effective April 1, 2005, procedure code J0880 (Aranesp) was discontinued for claims where the recipient has Medicaid as their sole coverage. For these recipients, Aranesp should be billed using the procedure code specific to your COS listed in the chart below.

Medicare as Primary Coverage

When Medicare is primary, code J0880 will be recognized by our system for purposes of deductible and/or coinsurance payment.

Aranesp Excluded from Nursing Facility Rates

Effective June 1, 2005, Aranesp was excluded from nursing facility rates. Aranesp provided to Medicaid fee-for-service nursing home residents is billed by the dispensing pharmacy.

Please refer to the June 2005 **Medicaid Update** announcing this change at:

www.health.state.ny.us/nysdoh/mancare/omm/2005/jun2005.htm#may

Physicians, Nurse Practitioners and Ordered Ambulatory Providers

For physicians, nurse practitioner and ordered ambulatory providers, these drugs are reimbursed at the provider's **actual acquisition cost.**

For **Practitioners,** the following codes are reimbursable:

COS/PROVIDER	DRUG	PROCEDURE CODE
0460, Physician 0469, Nurse Practitioner	Epoetin Alfa (**Epogen**) (for non-ESRD use) per 1,000 Units	Q0136
0460, Physician 0469, Nurse Practitioner	Darbepoetin Alfa (**Aranesp**) (for non-ESRD use) 1 mcg	Q0137
0460, Physician 0469, Nurse Practitioner	Filgrastim (**Neupogen**)	J1440 (300 mcg) J1441 (480 mcg)
0460, Physician 0469, Nurse Practitioner	Pegfilgrastim (**Neulasta**) 6 mg	J2505

Chemotherapy Clinics: For providers with rate code 3092 (Chemo Clinic Service), the following codes are reimbursable when billed on the same date of service as your chemotherapy clinic rate. You must bill for the clinic visit as a clinic claim on the x12 837I format and bill separately for the drug as an ordered ambulatory claim on the x12 837I, 837P or the NYS HCFA-1500 paper claim following the instructions in the companion guides and provider manuals.

NOTE: If you **do not have rate code 3092,** the drugs are included in your clinic rate reimbursement and **may not be billed separately.** *If you do have rate code 3092, use the following chart for billing.*

COS/PROVIDER	DRUG	PROCEDURE CODE

0160, Diagnostic & Treatment Center 0287, Hospital Outpatient Dept.	Epoetin Alfa (**Procrit**) (for non-ESRD use) per 1,000 Units	Bill **Q0136** as an Ordered Ambulatory Service
0160, Diagnostic & Treatment Center 0287, Hospital Outpatient Dept.	Darbepoetin Alfa (**Aranesp**) (for non-ESRD use) 1 mcg	Bill **Q0137** as an Ordered Ambulatory Service
0160, Diagnostic & Treatment Center 0287, Hospital Outpatient Dept.	Filgrastim (**Neupogen**)	Bill **J1440 (300 mcg) or J1441 (480 mcg)** as an Ordered Ambulatory Service
0160, Diagnostic & Treatment Center 0287, Hospital Outpatient Dept.	Pegfilgrastim (**Neulasta**) 6 mg	Bill **J2505** as an Ordered Ambulatory Service

For **Hemodialysis Clinics,** the following codes are reimbursable when billed on the same date of service as your dialysis clinic rate (1641 or 2883).

COS/PROVIDER	DRUG	PROCEDURE CODE
0160, Diagnostic & Treatment Center 0287, Hospital Outpatient Department	Epoetin Alfa (**Epogen**) (Per 1,000 Units)	Bill the Add-On **Rate Code - 1806** Bill the Add-On **Rate Code - 3106**
0160, Diagnostic & Treatment Center 0287, Hospital Outpatient Dept	Darbepoetin Alfa (**Aranesp**) (for ESRD on dialysis) 1 mcg	Bill **Q4054** as an Ordered Ambulatory Service

Questions can be directed to Mary Rondeau in the Bureau of Policy Development & Agency Relations at 518-473-2160.

eMedNY Update All Providers!

Electronic Remittances to Provide Retroactive Rate Adjustment Detail

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Effective **Monday, December 12, 2005** (Cycle 1477), **820 and 835 Electronic Remittances,** and the **820 Supplementary File** will provide more detailed information for specific claim types:

820 Remittance

The 820 transaction will provide a new value in the ADX segment (H1) to indicate other claim types reported on the 820 Supplementary File.

820 Supplementary File

This file has extensive changes in that it will provide claim detail and messages for:

- NYS State-submitted adjustments and voids.
- Retroactive rate adjustments (both reversals and corrections).
- Approved claims where the rate code was changed during adjudication (no message reported).
- Stop loss and kick newborn/maternal claims where the charge amount is not equal to the payment amount.

Please review the modified record layout provided in the 820 Supplemental Companion Guide carefully and adjust your applications accordingly.

835 Remittance

The 835 transaction will provide the PER segment to report more detail for NYS State-submitted adjustments and voids. In the event of a Retroactive rate adjustment, this segment will provide a message indicating "RETRO RATE REVERSAL" or "RETRO RATE CORRECTION."

Begin modifying your applications immediately to be ready for the December implementation.

To allow time for your programming changes, we have published draft Companion Guides on our website. Please visit NYHIPAADESK by clicking on www.emedny.org/HIPAA/index.html. You will be able to navigate directly to the draft Companion Guides.

A summary of changes is provided in each Companion Guide in the Introduction section entitled "CG MODIFICATION TRACKING."

Questions? Contact CSC at (800) 343-9000.

Nonemergency Transportation Claims
Driver's License Number and Vehicle License Plate Number

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As initially reported in the November 2004 **Medicaid Update,** all claims (electronic and paper) submitted to Medicaid by nonemergency ambulette transportation providers (category of service 0602) must contain the *Driver's License Number;* and the *Vehicle License Plate Number.*

Electronic Claims

The **837 Professional Nonemergency Transportation Companion Guide** has been updated to reflect the requirements established by the Department. For most claims:

- the *Driver's License Number* must be sent in the Referring Provider Name area (loop 2310A), in the Referring Provider Secondary Identification segment.
- the *Vehicle License Plate Number* must be sent in the Rendering Provider Name portion of the transaction (loop 2310B), in the Rendering Provider Secondary Identification segment.

Please see the Companion Guide for more detail and specific instructions for entering this information on claims for restricted recipients.

The **Nonemergency Transportation Companion Guide** is available at http://12.23.28.50/HIPAA/Phase_II_Transactions/transactions.html, then select "837 Professional Nonemergency Transportation Companion Guide".

Paper Claims

For paper claim submissions on Claim Form A:

- the *Driver's License Number* must be entered in Field 22, (Other Referring/Ordering Provider ID/License Number).
- the *Vehicle License Plate Number* must be entered in Field 21, (Service Provider ID/License Number)

PLEASE NOTE:

- *A new Edit (000267 - Vehicle License Plate/Driver's License Number Required) will be implemented in the claims adjudication system for nonemergency transportation claims (Category of Service 0602). The edit will insure the information is entered in the appropriate field for both paper and electronic submissions. Please follow the new billing instructions to avoid unnecessary delays/denials.*
- When reporting out-of-state Driver's License Numbers that may be greater than nine characters, *only the first nine characters should be reported.*

Questions? Contact Computer Sciences Corporation Provider Services at (800) 343-9000.

Attention Long Term Care Providers!

Partnership for Long-Term Care Program

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The **New York State Partnership for Long-Term Care** (Partnership), implemented in 1993, enables New Yorkers to **protect their assets** while remaining eligible for Medicaid by combining private long-term care insurance with the Medicaid program in a unique way.

If Partnership policyholders' long-term care needs exceed the duration of their policy coverage, they may apply for *Medicaid Extended Coverage*, a unique form of Medicaid for Partnership program participants, to help meet their ongoing long-term care needs while protecting their assets.

Currently, the Partnership offers **total asset protection insurance** only.

- This insurance product provides policyholders total asset protection at the time of their Medicaid application, which means eligibility for Medicaid Extended Coverage is based solely on Medicaid income rules.

Coming later this fall, new and more affordable Partnership insurance products will be available in addition to total asset protection plans.

- These new products will offer **dollar for dollar** asset protection, which means they will provide partial asset protection at the time of Medicaid application where protected assets equal the total amount of benefits paid by the insurance policy.

For more information, visit the Partnership website, www.nyspltc.org, or call 518 474-0662.

Timeliness of Electronic Remittances

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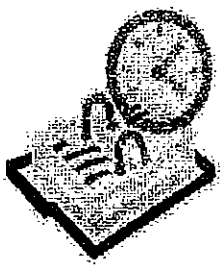
Providers who receive their remittances electronically will receive them by Monday, the same date that is on the check. Occasionally, when there are processing constraints, they will be sent a day or two later.



Providers who do not receive their electronic remittance by close of business on Wednesday MUST call the Help Desk at (800) 343-9000.

Electronic remittances over four weeks old cannot be recreated! It is important that providers pay close attention to their receipt of these remittances, and providers must save these remittance files safely on their own systems. *Remittance information over four weeks old may be obtained in paper format.*

For information on how to receive a paper version of an old remittance, visit www.emedny.org/HIPAA/QuickRefDocs/index.html. Click on "FOD-7003 Request Copy Remittance" (located under Supplementary Medicaid Documents). Information is also available via fax by calling the Provider Services Fax-On-Demand at (800) 370-5809, request document# 7003.

If you have any questions, please contact CSC Provider Services at (800) 343-9000.

- Encourage people with arthritis to protect themselves from the sun with protective clothing, sunglasses, and sunscreen that has a sun protection factor (SPF) of 15 or higher. Some types of arthritis can worsen with sun exposure.

Resources

NYS Department of Health Arthritis Program: www.health.state.ny.us/nysdoh/chronic/arthritis.htm

Arthritis Foundation: www.arthritis.org

Lupus Alliance of America: www.lupusalliance.org

Lupus Foundation of America: www.lupus.org

American College of Rheumatology: www.rheumatology.org/public/factsheets/nsaids.asp

U.S. Food and Drug Administration: www.fda.gov/cder/drug/infopage/celebrex/celebrex-ptsk.htm

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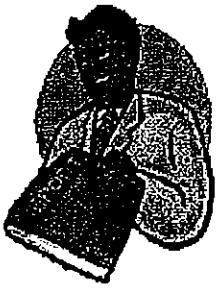

PATIENT EDUCATIONAL TOOLS

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This month's *Patient Educational Tools* features an article on

Influenza: Are you at Risk?

The Medicaid program encourages practitioners to **copy and distribute the following information** to their patients and to share it with their colleagues.

INFLUENZA
Are You at Risk?

What is Influenza (flu)?

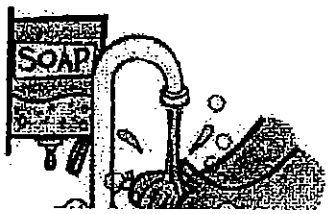
A contagious, respiratory infection caused by influenza viruses. It attacks the respiratory tract (nose, throat, lungs) and usually comes on sudden.

How is the flu spread?

The flu can be passed to others through sneezing, coughing or touching surfaces that have been infected. Adults may be able to infect others beginning one day **before** getting symptoms and up to seven days **after** getting sick. That means that you can give someone the flu before you know you're sick as well as when you are sick.

What can I do to protect myself and others?

You can take some simple steps to help prevent the spread of germs.



Get the flu vaccine

Cover your sneeze or cough with a tissue, not your hands.

Wash your hands, prevent the spread of germs

Give your immune system a boost by maintaining a healthy lifestyle, such as eating balanced meals, regular exercise & drinking plenty of fluids

- Avoid people who are sick
- If you start experiencing flu symptoms, call your health care provider. Certain medication can help if taken within the first 48 hours

Who should get the flu shot?

Given the uncertainties in dose and distribution, prioritization has been implemented for those at highest risk for complications of influenza. According to the CDC recommendations for 2005-06 flu season, the following priority groups should receive the flu vaccine:

- Individuals 6-months of age and older who have been displaced by Hurricane Katrina and are living in crowded group settings.
- Persons 65 years and older with or without co-morbid conditions.
- Residents of Long Term Care facilities.
- Persons 2 to 64 years with co-morbid* conditions.
- Children aged 6-23 months of age.
- Pregnant women.
- Health-care personnel providing direct patient care.
- Caregivers and household contacts of children less than 6-months old.

***Co-morbid:** The presence of one or more disorders (or diseases) in addition to a primary disease or disorder.

Who should NOT get the flu shot?

- People who have a severe allergy to chicken eggs.
- People who have had a severe reaction to an influenza vaccination in the past.
- People who developed Guillain-Barre syndrome (GBS) within six weeks of getting an influenza vaccine previously.
- Children less than six months of age.
- People who are sick with a fever. (These people can get vaccinated once their symptoms lessen.)

The flu is a serious disease and can have serious complications. If you are uncertain as to whether you should receive the flu shot, check with your physician.

How do I know if I have the flu?

Symptoms of the flu usually come on quickly and the typical flu season is between the months of November-April. Some symptoms of flu are:

- fever (usually high)
- headache
- extreme tiredness
- dry cough
- sore throat
- runny or stuffy nose
- muscle aches
- gastrointestinal symptoms, such as nausea, vomiting and diarrhea, are much more common among children than adults

How do you treat the flu?

If you have seen a physician, follow his/her recommendations

- Rest.
- Drink lots of fluids such as water, juice, tea, and non-carbonated beverages.
- Over the counter medications can help treat the symptoms (check with your physician).

When should I call my doctor?

If you experience shortness of breath, chest discomfort, ear pain, high fever or you have a chronic condition, contact your health care professional **immediately** so that they can recommend what is the best treatment for you.

Education

Being aware of symptoms of the flu and taking some simple steps to prevent the spread of germs is essential. Prevention is the first step, vaccinate, educate others & teach others the importance of proper hygiene. **Stay healthy!**

Source adapted from:
New York State Department of Health, Influenza fact sheet
Center for Disease Control and Prevention, Influenza (flu) protect yourself & your loved ones. Sept 2, 2005
U.S. Food and Drug Administration Beat the Winter bugs, hold your own against colds and flu.

For more information on Influenza, you can visit the following websites:
New York State Department of Health at www.health.state.ny.us/nysdoh/flu/flu_fact_sheet.htm
Center for Disease Control and Prevention at www.cdc.gov/flu/keyfacts.htm
U.S. Food and Drug Administration at www.fda.gov

The NYS Medicaid Program reimburses for medically necessary care, services, and supplies needed in the diagnosis and treatment of Influenza.

Attention

Portable X-Ray Demonstration Program Providers

Residential Health Care Facilities

Intermediate Care Facilities for the Developmentally Disabled

Portable X-Ray Demonstration Project Reinstated

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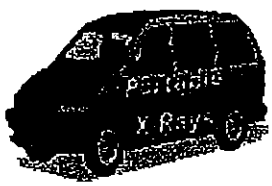
The Portable X-Ray Demonstration Project has resumed.

This program ended June 30, 2004, but was recently reinstated through June 30, 2006 by Chapter 114 of the Laws of 2005.

Providers enrolled in the Portable X-Ray Demonstration Project were notified by letter that they may begin billing for portable x-ray services beginning September 14, 2005.



This demonstration project is for services provided to residents of Residential Health Care Facilities (RHCFs) or Intermediate Care Facilities for the Developmentally Disabled (ICF/DDs) **whose only health coverage is Medicaid.**

Questions? Contact the Bureau of Policy Development and Agency Relations at: 518-473-2160.

Seminar Schedule and Registration

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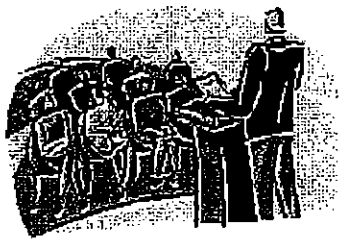
Computer Sciences Corporation (CSC) announces a schedule of seminars to be offered to providers and their billing staff.

Seminar locations and dates are available at the eMedNY website. Registration is fast and easy.

Go to www.emedny.org/training/index.aspx to register for the eMedNY Training Seminar appropriate for your provider category and location.

If you are unable to access the internet to register, please contact CSC's call center at (800) 343-9000, to obtain a registration form. You may also request seminar schedule and registration information by contacting CSC's Fax on Demand at (800) 370-5809.

Please refer to these resources frequently for additional seminar offerings.



CSC representatives look forward to meeting with you at upcoming seminars!

2005 Medicare Coinsurance Enhancement for Physicians and DME Providers

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The 2005-06 State Budget requires that each physician and durable medical equipment (DME) provider that received Medicare coinsurance payments during the period April 1, 2005 through June 30, 2005 also receive a "2005 Coinsurance Enhancement" payment in an amount determined as follows:

- The Department of Health will determine the ratio of **each** physician's and DME provider's Medicare coinsurance payments to the total of all Medicaid coinsurance payments made to physicians and DME providers respectively, during the April 1, 2005 through June 30, 2005 period. This ratio will be expressed as a percentage.
- **For each physician,** the Department will then multiply the percentage by $4,700,000.
- **For each DME provider,** the Department will then multiply the percentage by $300,000

  These are the amounts appropriated by the Legislature.

- The result of such a calculation represents the 2005 Coinsurance Enhancement, and will only be paid to physicians and durable medical equipment providers that received a Medicare coinsurance payment during the time period cited above.

The Department has determined that approximately 17,000 physicians and 530 DME providers will receive a coinsurance enhancement payment. The payment will be made in separate checks mailed to qualifying physicians and DME providers. This payment will most likely be made during **December 2005.**

These checks will be mailed to providers directly from the Office of the State Comptroller. Eligible providers will receive only a check - with no supporting documentation. You will be able to identify the check by the message "2005-Coinsur-Enhance" which will appear on the payment stub.

If you have any questions, please call Computer Sciences Corporation Provider Relations at (800) 522-5518 or (518) 257-4104.

Fraud impacts all taxpayers.

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Do you suspect that a recipient or a provider has engaged in fraudulent activities?

Please call:

1-877-87FRAUD

PROVIDER SERVICES

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Missing Issues?
The Medicaid Update, now indexed by subject area, can be accessed online at the New York State Department of Health website: http://www.health_care/medicaid/program/update/main.htm
Hard copies can be obtained upon request by calling **(518) 474-9219.**

Would You Like Future Updates Emailed To You?
Email your request to our mailbox, MEDUPDTE@health.state.ny.us
Let us know if you want to continue receiving the hard copy in the mail in addition to the emailed copy.

Do You Suspect Fraud?
If you suspect that a recipient or a provider has engaged in fraudulent activities, please call the fraud hotline at: 1-877-87FRAUD. Your call will remain confidential.

As a Pharmacist, Where Can I Access the List of Medicaid Reimbursable Drugs?
The list of Medicaid reimbursable drugs is available at: http://www.eMedNY.org/info/formfile.html

Questions About an Article?
For your convenience each article contains a contact number for further information, questions or comments.

Do You Want Information On Patient Educational Tools and Medicaid's Disease Management Initiatives?
Contact Department staff at (518) 474-9219.

Questions About HIPAA?
Please contact CSC Provider Services at (800) 343-9000.

Address Change?
Questions should be directed to CSC at (800) 343-900, option 5.

Fee-for-service Provider Enrollment
A change of address form is available at: http://www.emedny.org/info/ProviderEnrollment/Provider%20Maintenance%20Forms/6101-Address%20Change%20Form.pdf.

Rate-based/Institutional Provider Enrollment
A change of address form is available at: http://www.emedny.org/info/ProviderEnrollment/Provider%20Maintenance%20Forms/6106-Rate%20Based%20Change%20of%20Address%20Form.pdf

Billing Question? Call Computer Sciences Corporation:
Provider Services (800) 343-9000.

Comments and Suggestions Regarding This Publication?
Please contact the editor, Timothy Perry-Coon at MEDUPDTE@health.state.ny.us or via telephone at (518) 474-9219 with your concerns.

The State Department of Health welcomes your comments or suggestions regarding the Medicaid Update.

Please send suggestions to the editor, Timothy Perry-Coon:

NYS Department of Health
Office of Medicaid Management
Bureau of Program Guidance
99 Washington Ave., Suite 720
Albany, NY 12210
(e-mail MEDUPDTE@health.state.ny.us)

The Medicaid Update, along with past issues of the Medicaid Update, can be accessed online at the New York State Department of Health web site:http://www.health_care/medicaid/program/update/main.htm">

Please Note

Some documents on this page are saved in the Portable Document Format (PDF). If it's not already on your computer, you'll need to download the latest free version of Acrobat Reader.

Revised: November 2005